EXHIBIT A

State of Alabama
Unified Judicial System
Form ARCiv-93 Rev. 9/18

COVER SHEET
CIRCUIT COURT - CIVIL CASE
(Not For Domestic Relations Cases)

Cas
11
Date of Filing: 03/30/2022
Judge Code:

GENERAL INFORMATION

IN THE CIRCUIT COURT OF CALHOUN COUNTY, ALABAMA
LORIE A. MOORE v. ETHICON US, LLC ET AL

First Plaintiff: ☐ Business ☑ Individual ☐ Government ☐ Other

First Defendant: ☑ Business ☐ Individual ☐ Government ☐ Other

NATURE OF SUIT: Select primary cause of action, by checking box (check only one) that best characterizes your action:

TORTS: PERSONAL INJURY
- ☐ WDEA - Wrongful Death
- ☐ TONG - Negligence: General
- ☐ TOMV - Negligence: Motor Vehicle
- ☐ TOWA - Wantonness
- ☑ TOPL - Product Liability/AEMLD
- ☐ TOMM - Malpractice-Medical
- ☐ TOLM - Malpractice-Legal
- ☐ TOOM - Malpractice-Other
- ☐ TBFM - Fraud/Bad Faith/Misrepresentation
- ☐ TOXX - Other: _____

TORTS: PERSONAL INJURY
- ☐ TOPE - Personal Property
- ☐ TORE - Real Properly

OTHER CIVIL FILINGS
- ☐ ABAN - Abandoned Automobile
- ☐ ACCT - Account & Nonmortgage
- ☐ APAA - Administrative Agency Appeal
- ☐ ADPA - Administrative Procedure Act
- ☐ ANPS - Adults in Need of Protective Service

OTHER CIVIL FILINGS (cont'd)
- ☐ MSXX - Birth/Death Certificate Modification/Bond Forfeiture Appeal/ Enforcement of Agency Subpoena/Petition to Preserve
- ☐ CVRT - Civil Rights
- ☐ COND - Condemnation/Eminent Domain/Right-of-Way
- ☐ CTMP - Contempt of Court
- ☐ CONT - Contract/Ejectment/Writ of Seizure
- ☐ TOCN - Conversion
- ☐ EQND - Equity Non-Damages Actions/Declaratory Judgment/ Injunction Election Contest/Quiet Title/Sale For Division
- ☐ CVUD - Eviction Appeal/Unlawful Detainer
- ☐ FORJ - Foreign Judgment
- ☐ FORF - Fruits of Crime Forfeiture
- ☐ MSHC - Habeas Corpus/Extraordinary Writ/Mandamus/Prohibition
- ☐ PFAB - Protection From Abuse
- ☐ EPFA - Elder Protection From Abuse
- ☐ QTLB - Quiet Title Land Bank
- ☐ FELA - Railroad/Seaman (FELA)
- ☐ RPRO - Real Property
- ☐ WTEG - Will/Trust/Estate/Guardianship/Conservatorship
- ☐ COMP - Workers' Compensation
- ☐ CVXX - Miscellaneous Circuit Civil Case

ORIGIN: F ☑ **INITIAL FILING** | A ☐ **APPEAL FROM DISTRICT COURT** | O ☐ **OTHER**
R ☐ **REMANDED** | T ☐ **TRANSFERRED FROM OTHER CIRCUIT COURT**

HAS JURY TRIAL BEEN DEMANDED? ☐ **YES** ☑ **NO**
Note: Checking "Yes" does not constitute a demand for a jury trial. (See Rules 38 and 39, Ala.R.Civ.P, for procedure)

RELIEF REQUESTED: ☑ **MONETARY AWARD REQUESTED** ☐ **NO MONETARY AWARD REQUESTED**

ATTORNEY CODE:
MOR122 — 3/30/2022 12:06:29 PM (Date) — /s/ STEVE R MORRIS (Signature of Attorney/Party filing this form)

MEDIATION REQUESTED: ☐ **YES** ☑ **NO** ☐ **UNDECIDED**

Election to Proceed under the Alabama Rules for Expedited Civil Actions: ☐ **YES** ☑ **NO**

IN THE CIRCUIT COURT OF CALHOUN COUNTY, ALABAMA

LORIE A. MOORE,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**CASE NO.: 2022-CV-**
	)	
JOHNSON & JOHNSON,	)	
	)	
ETHICON US, LLC,	)	
	)	
JANSSEN ORTHO, LLC,	)	
	)	
JANSSEN RESEARCH & DEVELOPMENT, LLC,	)	
	)	
JANSSEN PHARMACEUTICALS, INC.,	)	
	)	
ORTHO-MCNEIL PHARMACEUTICALS, INC.,	)	
	)	
TEVA BRANDED PHARMA-CEUTICAL PRODUCTS R&D, INC.,	)	
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
DR. MOHAMMAD F. ISMAIL,	)	
	)	
and Defendants A, B, C, D, E, and F, being those Persons, Firms or Corporations whose acts, omissions, negligence and/or other wrongful conduct caused or contributed to the Plaintiff's Injuries and whose true names and Identities are presently unknown to the Plaintiff but will be submitted by amendment when correctly ascertained,	)	
	)	
Defendants.	)	

COMPLAINT

COMES NOW the Plaintiff, Lorie A. Moore and states her claims for relief against Defendants Johnson & Johnson and its subsidiary, Ethicon US, LLC, Dr. Mohammad F. Ismail, Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc., Ortho-McNeil Pharmaceuticals, Inc., Janssen Research & Development, LLC, f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC, Janssen Ortho, LLC, Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries LTD., (hereinafter collectively referred to as "Defendants"),and A, B, C, D, E, F, and G, whether singular or plural, being those persons, firms or entities who or which proximately caused or contributed to the Plaintiff's personal injuries and the other damages as complained of herein whose true names are unknown to the Plaintiff but will be added by amendment when correctly ascertained, and shows and states the claims of Plaintiff against the said Defendants as follows:

1. This Court has jurisdiction of this controversy on grounds that the Plaintiff is an individual resident of the state of Alabama, and that the Defendants all caused tortious injury or do business in this state and county, and the Defendants caused tortious injury to Plaintiff by conduct occurring in this state and county and the Defendants are otherwise subject to the jurisdiction of this court. Defendants A, B, C, D, E, and F, whose true names are unknown to Plaintiff, but will be added by amendment when correctly ascertained, each committed tortious acts, or breached contracts or other duties in this state and county as set forth below.

2. Defendant Johnson and Johnson and its subsidiary, Ethicon US, LLC was the entity which did manufacture, create, design, test, label, package, distribute, market, sell, advertise, fail to warn about, and otherwise handle and placed the Prolene Mesh product in the stream of commerce.

3. Johnson and Johnson and its subsidiary, Ethicon US, LLC, does business in Alabama and in Calhoun County, and at all times relevant, sold in Alabama and Calhoun County, the aforementioned medical device Prolene Mesh, and is otherwise subject to this Court's jurisdiction. The defendant does business by agent in this state and county and has caused tortious injury in this state and county by manufacturing and selling a dangerous and defective product. Each defendant acting directly and by agent, is legally responsible to plaintiff as a consequence of that defendant's (A) transacting any business in this state, (B) contracting to supply services or goods in this state, (C) causing tortious injury or damage by an act or omission in this state, (D) causing tortious injury or damage in this state by act or omission outside this state and the defendant regularly does or solicits business, or engages in any other persistent course of conduct or derives of substantial revenue from goods used or consumed or services rendered in this state, (E) causing injury or damage in this state to a person by breach of warranty expressly or implied made in the sale of goods outside this state when the defendant might reasonably have expected such other person to use, consume, or be affected by the goods in this state, and the defendant also regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state, and otherwise had or has some minimum contacts with this state and, under the circumstances, it is

fair and reasonable to require each defendant to come to this state to defend an action. The amount in controversy in this civil action exceeds the jurisdictional minimum for the circuit courts. This court has jurisdiction hereof both as to the subject matter and in personam.

4. Plaintiff also brings the action to recover damages for personal injuries, restitution, refunds, and/or for equitable and declaratory relief against all defendants, and Defendants Johnson and Johnson and its subsidiary, Ethicon US, LLC, which developed, tested, designed, marketed, distributed, prescribed, and sold the medical device Prolene Mesh. This defendant set about to sell and market the medical device Prolene Mesh, throughout the state of Alabama and to Plaintiff in such a manner that their conduct was a substantial proximate cause of the injuries suffered by the Plaintiff Lorie Moore. Plaintiff reasserts against Defendants Johnson and Johnson and its subsidiary, Ethicon US, LLC, Plaintiff's claims for negligence, wantonness, AEMLD violation, failure to warn, fraudulent suppression, misrepresentation, deceit, breach of express and implied warranties, and other claims as stated in the Complaint, which are incorporated herein by reference.

5. In addition to the foregoing, Plaintiff Lorie A. Moore, brings this action against Defendants Dr. Mohammad F. Ismail, Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; Ortho-McNeil Pharmaceuticals, Inc.; Janssen Research & Development, LLC, f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC; Janssen Ortho, LLC; Johnson & Johnson; Teva Branded Pharmaceutical Products R&D, Inc.; Teva Pharmaceuticals USA, Inc.; Johnson and Johnson and its subsidiary, Ethicon US, LLC

and Teva Pharmaceutical Industries LTD., (hereinafter collectively referred to as "Defendants") and A, B, C, D, E, and F, whether singular or plural, being those persons, firms or entities who or which proximately caused or contributed to the Plaintiff's personal injuries and the other damages as complained of herein whose true names are unknown to the Plaintiff but will be added by amendment when correctly ascertained.

6. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' wrongful conduct in connection with the prescription drug, Elmiron®, which is indicated for the treatment of bladder pain and/or the discomfort associated with interstitial cystitis (IC).

7. At all relevant times, upon information and belief, Elmiron was designed, developed, tested, manufactured, packaged, distributed, labelled, promoted, marketed, and/or sold by Defendants pursuant to a joint venture licensing agreement.

8. At all relevant times, Defendants conducted business throughout Calhoun County and the State of Alabama, Elmiron was sold and marketed throughout Calhoun County and the State of Alabama, and Defendants' wrongful conduct occurred, in part, in Calhoun County in the State of Alabama.

9. Defendant Dr. Mohammad F. Ismail is a resident of Calhoun County and may be served with process at his place of business at 1011 Leighton Avenue, Anniston, AL 36207. Ismail and the other Defendants are subject to the jurisdiction and venue of this Court, pursuant to the provisions of Alabama Code Section 6-5-546 in that this is the county wherein the acts or omissions constituting the breaches of the standards of care by the defendants actually occurred.

10. Defendant Teva Branded Pharmaceutical Products R&D, Inc. is a Delaware

Corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

11. At all relevant times, Defendant Teva Branded Pharmaceutical Products R&D, Inc. regularly and continuously did business in the United States, including in the State of Alabama, and was also engaged in the design, testing, labeling, packaging, marketing, advertising, distribution and/or sale of Elmiron, individually and/or through or with its partners and joint venturers.

12. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware Corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

13. At all relevant times, Defendant Teva Pharmaceutical USA, Inc. regularly and continuously did business in the United States, including in the State of Alabama, and was also engaged in the design, testing, labeling, packaging, marketing, advertising, distribution and/or sale of Elmiron, individually and/or through or with its partners and joint venturers.

14. Defendants Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceuticals USA, Inc. are subsidiaries of the parent company Defendant Teva Pharmaceutical Industries Ltd. with Global Headquarters at 5 Basel Street, Petach Tikva 49131, Israel, and U.S. Headquarters at 400 Interpace Parkway, #3, Parsippany, New Jersey 07054.

15. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd., made consequential decisions and/or took significant actions concerning inter alia, the design, testing, labeling, packaging, marketing, advertising, distribution sale,

promotion, and/or regulatory approval of Elmiron, individually and/or through or with its partners and joint venturers.

16. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd.'s decisions and/or actions with respect to Elmiron impacted, inter alia, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA-approval of Elmiron in the United States, including in Alabama.

17. Defendant Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc., ("Janssen Pharma") is a New Jersey corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

18. Upon information and belief, Defendant Janssen Pharma made consequential decisions and/or took significant actions concerning, inter alia, the design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the United States, including in Alabama.

19. Upon information and belief, as part of its business, Defendant Janssen Pharma engages in the design, testing, labeling, packaging, marketing, advertising, distributing and/or selling of pharmaceutical products, including Elmiron.

Ortho Pharma

20. Defendant Ortho-McNeil Pharmaceuticals, Inc. ("Ortho Pharma") is a corporation organized under Delaware law with its principal place of business in 1000 US Highway 202, Raritan, New Jersey 08869.

21. Upon information and belief, Defendant Ortho Pharma made consequential decisions and/or took significant actions concerning, inter alia, the

design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the United States, including in Alabama.

22. Defendant, Janssen Research & Development, LLC, f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC (hereinafter "Janssen R&D") is a limited liability company under the laws of New Jersey, with its principal place of business located at One Johnson and Johnson Plaza, New Brunswick, New Jersey 08933.

23. Upon information and belief, Defendant Janssen R&D made consequential decisions and/or took significant actions concerning inter alia, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or regulatory approval of Elmiron.

24. Upon information and belief, Defendant Janssen R&D has transacted and conducted business within the State of Alabama and has derived substantial revenue from goods and products disseminated and used in the State of Alabama.

25. Upon information and belief, as part of its business, Defendant Janssen R&D is involved in the research, development, sales, and/or marketing of pharmaceutical products, including Elmiron.

26. Upon information and belief, and at all relevant times Defendant, Janssen R&D, was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Elmiron.

27. Defendant Janssen Ortho, LLC ("Janssen Ortho") is a limited liability company organized under Delaware law with its principal place of business in Gurabo 00777, Puerto Rico and may be served by its registered agent, C T Corporation System

2 North Jackson Street, Suite 605, Montgomery, AL 36104

28. Defendant Janssen Ortho's sole member is OMJ PR Holdings, a corporation incorporated in Ireland with a principal place of business in Puerto Rico.

29. Upon information and belief, Defendant Janssen Ortho made consequential decisions and/or took significant actions concerning, inter alia, the design, testing, marketing, promotion, labeling and regulatory approval of Elmiron.

30. Upon information and belief, Defendant Janssen Ortho manufacturers and/or packages Elmiron, on behalf of Janssen Pharma, for sale throughout the United States and in Alabama specifically.

31. Upon information and belief, and at all relevant times, Defendant, Janssen Ortho, was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Elmiron.

Johnson & Johnson

32. Defendant Johnson & Johnson (hereinafter referred to as "J&J") is a New Jersey corporation, which has its principal place of business at One Johnson and Johnson Plaza, New Brunswick, New Jersey 08933.

33. Upon information and belief, at all relevant times, Defendants Janssen Pharma, Ortho Pharma, Janssen R&D, and Janssen Ortho have been wholly owned subsidiaries of Defendant J&J with the profits of each inuring to Defendant J&J's benefit.

34. Upon information and belief, as part of its business, Defendant J&J and its "family of companies," is involved in the research, development, sale, and/or marketing of pharmaceutical products, including Elmiron.

35. Upon information and belief, Defendant J&J made consequential decisions and/or took significant actions concerning inter alia, the design, marketing, promotion, labeling and/or regulatory approval of Elmiron.

36. Upon information and belief, Defendant J&J's decisions and/or actions with respect to Elmiron impacted, inter alia, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA-approval of Elmiron in the United States, including Alabama.

37. Defendants A, B, C, D, E and F, whether singular or plural, are those persons, firms or entities who or which proximately caused or contributed to the Plaintiff's damages as complained of herein whose true names are unknown to the Plaintiff but will be added by amendment when correctly ascertained. As used in this Complaint, the general word "defendants" includes, incorporates, and is defined to mean, not only the named defendants, but also defendants A, B, C, D, E and F, being those persons, firms or entities who or which proximately caused or contributed to the Plaintiff's personal injuries and the other damages as complained of herein whose true names are unknown to the Plaintiff but will be added by amendment when correctly ascertained.

38. At all relevant times, Defendants expected or should have expected that their acts would have consequences within Calhoun County, Alabama.

FACTUAL ALLEGATIONS

I. Brief History of Elmiron

39. At all relevant times, all Defendants were in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell and/or

distribute Elmiron for the treatment of the bladder pain and/or discomfort with interstitial cystitis.

40. Defendants' fraudulent and illegal conduct with respect to Elmiron caused thousands of individuals, including Plaintiff Lorie A. Moore, to develop severe injuries, including but not limited to, pigmentary maculopathy.

41. Interstitial cystitis ("IC"), which is also sometimes referred to as "painful bladder syndrome", is a chronic bladder condition in which individuals experience bladder pain, pelvic pain, urinary frequency, urinary urgency, and/or nocturia.

42. According to the U.S. Centers for Disease Control, IC may impact as many as 5.1 out of 100,000 Americans and up to 12% of U.S. women may have early symptoms of IC.

43. IC is known to affect more women than men.

44. The American Urological Association ("AUA") established guidelines, separating treatment options into six (6) tiers of increasingly invasive therapies for the treatment of IC. The treatments listed range from minimally invasive interventions, like simple lifestyle changes, to increasingly more invasive interventions, like invasive diagnostic studies or surgery. AUA recommends second-line treatment of IC to incorporate multi-modal pain management approaches including manual therapy and oral therapy options such as pentosane poly sulfate (Elmiron). Elmiron is not the best nor the only option for treating interstitial cystitis.

45. There is no known cause of interstitial cystitis.

46. There is no known cure for interstitial cystitis and the condition is permanent or chronic.

47. On approximately June 11, 1991, Baker Norton Pharmaceuticals, a division of Ivax Pharmaceuticals, ("Baker Norton") submitted a New Drug Application ("NDA") for pentosane polysulfate sodium (NDA: 020193) (hereafter "original NDA").

48. Pentosane polysulfate sodium is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative.

49. Pentosane polysulfate sodium is sold under the brand name Elmiron.

50. According to the U.S. Food and Drug Administration ("FDA"), "the documentation required in a NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.

51. Upon information and belief, FDA deemed the original NDA non-approvable in approximately 1993.

52. Upon information and belief, in response, Baker Norton submitted additional materials in support of the application, for FDA review.

53. Upon information and belief, FDA issued a second non-approvable letter in approximately 1994.

54. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995.

55. Upon information and belief, Baker Norton, again, submitted additional materials, in support of the application, for FDA review.

56. On September 26, 1996, FDA approved Elmiron for relief of pain or discomfort associated with IC.

57. The proposed label, approved by FDA, included a Package Insert, directed at physicians and other healthcare providers, as well as a Medication Guide, directed at patients.

58. Beginning in approximately 1996, when Elmiron was first approved by FDA, neither its Package Insert, nor its Medication Guide contained any warnings or information regarding the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

59. Upon information and belief, from approximately 1996, when the NDA was approved, until approximately 1997, Baker Norton owned the trademark for Elmiron.

60. Upon information and belief, in approximately 1997, Baker Norton was subsequently purchased by Teva Pharmaceutical Industries, Ltd., and/or Teva Pharmaceuticals, Inc.

61. Upon information and belief, as part of that transaction, Teva Pharmaceutical Industries, Ltd., and/or Teva Pharmaceuticals, Inc. purchased the assets and liabilities of Baker Norton.

62. Upon information and belief, Elmiron is a Registered Trademark of Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and/or Teva Pharmaceutical Industries Ltd., under license to Defendant Janssen Pharma.

63. Upon information and belief, from approximately August 2002 until August 2004, Defendant Janssen R&D held the NDA for Elmiron.

64. Upon information and belief, from July 2004 until August 2008, Defendant Ortho Pharma held the NDA for Elmiron.

65. Upon information and belief, since August 2008, Janssen Pharma, had held the NDA for Elmiron and continues to manufacture and/or distribute Elmiron in the United States.

66. There is no generic, non-bioequivalent form of Elmiron sold in the United States.

67. Upon information and belief, given the chronic and permanent nature of IC, Defendants anticipated (or reasonably should have anticipated), that patients taking Elmiron would likely do so indefinitely.

68. Upon information and belief, sales of Elmiron generate approximately $150 million in annual revenue in the United States.

II. Defendants Knew of the Elmiron Defect but Failed to Warn or Test

69. From approximately 1997 to the present, Defendants have received multiple Adverse Event Reports ("AER") from medical professionals concerning Elmiron. These AERs included serious visual complication believed to be associated with Elmiron use, ranging from retinal hemorrhage to macular degeneration to even unilateral blindness.

70. The reports of serious visual complications were not unique to the United States and, upon information and belief, serious visual complications were reported to Defendants and recorded in other AER databases around the world, where Elmiron was sold, like EudraVagilance, the European Medicines Agency's ("EMA") adverse event database.

71. It is widely recognized and accepted in the pharmaceutical industry that reported AERs represent only a small fraction of adverse events associated with and/or

caused by a particular drug.

72. More recently, since approximately 2018, outside, independent studies and reports, documented in medical literature raise similar concerns regarding Elmiron's safety and propensity for causing serious visual complications including, but not limited to, pigmentary maculopathy.

73. In approximately May 2018, Emory Eye Center in Atlanta, Georgia, conducted a case study of six adult patients, who were treating their IC symptoms with Elmiron. These physicians observed and documented significant pigmentary maculopathy in all six patients, who each had a long-history of Elmiron use.

74. In approximately May 2018, Emory Eye Center in Atlanta, Georgia, published a case study of six adult patients, who were treating their IC symptoms with Elmiron. The Emory physicians observed and documented significant pigmentary maculopathy in all six patients, who each had a long-history of Elmiron use.

75. In approximately April 2019, the Emory Eye Center published a further case study of ten patients. The doctors reported that over the last four years, patients who did not treat IC with pentosane polysulfide sodium were not experiencing pigmentary maculopathy.

76. The first clinical population-based study came from Kaiser Permanente in 2019. Kaiser Permanente conducted a study based of 4.3 million patients. Patients showed clear evidence of this specific maculopathy, which was believed associated with Elmiron exposure.

77. The Kaiser Permanente research was presented at the "AAO 2019", the annual meeting of the American Academy of Ophthalmology at Moscone Center, San

Francisco. The study revealed that eye damage increased with the quantity of Elmiron intake.

78. A Harvard Medical School case study, published in 2019, a female with a history of eighteen years of Elmiron use at a low dose of 200mg/day. She initially presented with symptoms that included blurry vision, difficulty seeing at night, and pigmentary changes in the retina. Two years later, she returned for evaluation; her eye examination revealed more extensive eye damage, consistent with pigmentary maculopathy. The Harvard physicians concluded that long-term Elmiron use results in progression of pigmentary maculopathy, even if the drug is stopped.

79. A study published in April 2020, by the Canadian Ophthalmological Society concluded, inter alia, the prevalence of Elmiron-induced macular toxicity posed a "significant risk" to patients taking Elmiron.

80. Upon information and belief, beginning in approximately 2019, Defendants took steps to warn consumers and physicians in other countries of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron.

81. For instance, in approximately September of 2019, Defendants revised the Elmiron label in Canada to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron, as follows:

82. Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosane polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptations. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy,

particularly those with long-term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

83. Likewise, in approximately 2019, Defendants "agreed" with an EMA Committee's recommendation that Elmiron's label be changed to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with long-term use of Elmiron.

84. The Elmiron label in EMA countries now warns: All patients should have an ophthalmologic examination after 6 months of use of PPS for early detection of pigmentary maculopathy, and if there are no pathologic findings, regularly after 5 years of use (or earlier, in case of visual complaints). However, in case of relevant ophthalmologic findings, a yearly examination should be conducted. In such situations, treatment cessation should be considered.

85. The Elmiron label used in EMA countries further admits that "eye disorders", like pigmentary maculopathy "might not be easily recognized by the urology community".

86. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

87. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate, at all times, for as long as the drug remained available for sale in the United States.

88. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Elmiron, after the Elmiron NDA was approved, for as long as the drug remained available for sale

in the United States.

89. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

90. Upon information and belief, by approximately 2001, Defendants had reasonable evidence of a causal association between serious vision-related injuries and Elmiron use.

91. Upon information and belief, by approximately 2001, Defendants learned Elmiron use could cause serious vision-related injuries.

92. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

93. Upon information and belief, despite understanding Elmiron could cause vision-related injuries, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering

vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

94. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual injuries, including, but not limited to, pigmentary maculopathy.

95. Upon information and belief, despite understanding patients taking Elmiron would likely remain on the medication for long periods of time, Defendants' failed to test and study the long-term safety and efficacy of the drug, prior to seeking FDA approval.

96. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron's long-term effects, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual injuries, including, but not limited to, pigmentary maculopathy.

97. Upon information and belief, despite post-approval adverse event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Elmiron, particularly in patients who used the drug for long periods of time.

98. Upon information and belief, from the date all Defendants received FDA-approval to market Elmiron in the United States, Defendants each of them made, distributed, marketed, and sold Elmiron without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Elmiron was associated with and/or could cause

retina damage in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Elmiron with regard to retina damage.

99. Upon information and belief, Defendants concealed and/or failed to completely disclose their knowledge that Elmiron was associated with and/or could cause retina damage as well as their knowledge that they had failed to fully test or study said risk.

100. Upon information and belief, all Defendants ignored the association between the use of Elmiron and the risk of developing permanent and disfiguring visual complications, including, but not limited to, pigmentary maculopathy and retina damage.

101. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of retina damage of Elmiron, but similar efficacy compared to less potent products.

102. Upon information and belief, all Defendants failed to provide adequate instructions to U.S. healthcare professionals and patients regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

103. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

104. Upon information and belief, all Defendants failed to warn U.S. healthcare

professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, that the risk of potentially serious visual complications increases the longer a patient continues to use Elmiron.

105. Upon information and belief, all Defendants failed to warn and/or to provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop taking Elmiron in the event that potentially serious visual complications developed while using Elmiron.

106. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of retina damage to patients taking Elmiron as to compared to other similarly efficacious pharmaceutical products.

107. All of Defendants' failures to provide adequate instructions and/or disclose information—which Defendants each possessed regarding the failure to adequately test and study Elmiron for the risk of serious visual complications—further, rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

108. Despite AERs from healthcare professionals and consumers around the world from approximately 1997 until approximately September 2019, Elmiron never warned—in any country or market—of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

109. Today, Defendants' U.S. Elmiron does not warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including,

but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

110. To this day, upon information and belief, Defendants have made no attempt to warn U.S. healthcare professionals and/or consumers of the risks of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

III. Plaintiff-Specific Allegations

111. Plaintiff, Lorie A. Moore, brings this case for damages associated with her use of the pharmaceutical drug Elmiron, which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Plaintiff Lorie A. Moore suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of her use of Elmiron.

112. Upon information and belief, Plaintiff Lorie A. Moore was diagnosed by her physician, Dr. Brandon Richmond with Interstitial Cystitis (IC), which is a chronic bladder condition resulting in recurring discomfort or pain in the bladder or surrounding pelvic region. People with IC usually have inflamed or irritated bladder walls which can cause scarring and stiffening of the bladder.

113. Upon information and belief, at the direction of her physician, Dr. Brandon Richmond, Plaintiff Lorie A. Moore began taking Elmiron continuously and daily from approximately 2004, for the treatment of her IC-related pain.

114. In approximately April 2020, Plaintiff was diagnosed with vision-related injuries by her optometrist, Josh Tinsley, O.D. at Kazi Ophthalmology in Anniston, Alabama.

115. It was only just months prior to the date of the filing of this Complaint that

Plaintiff first knew, or had any reason to know, that her vision-related injuries, could have been caused by Elmiron.

116. As a direct result of her long-term exposure to Defendants' Elmiron product, Plaintiff suffered serious visual injuries, including, but not limited to, severe vision degradation, and loss of night vision.

117. Upon information and belief, Plaintiff's ingestion of Elmiron caused her injuries.

118. As a direct and proximate result of Plaintiff Lorie A. Moore being prescribed Elmiron from approximately 2004 to recently, and also prescribed again by Dr. Mohammad Ismail in May 13, 2020, Plaintiff suffered significant injuries, such as those described above.

119. As direct and proximate result of Defendants' misconduct, as described herein, Plaintiff suffered serious vision-related injuries, due to Plaintiff's exposure to Elmiron.

120. By reason of the foregoing acts and omissions, Plaintiff has suffered serious visual injuries, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and medical treatment.

121. By reason of the forgoing acts and omissions Plaintiff has suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm.

122. Plaintiff accordingly seeks damages associated with these injuries.

123. Plaintiff Lorie A. Moore would not have used Elmiron had any or all of Defendants' properly disclosed the risks associated with its use.

124. Plaintiff Lorie A. Moore's injuries could have been avoided or would have been less severe had any or all of Defendants properly disclosed the risks associated with its use.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

125. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold information from the Plaintiff, her healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

126. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, her family members, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

127. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and /or treat known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

128. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Elmiron.

129. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Elmiron was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Elmiron knowing such

information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Elmiron use. They did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

130. Further, Defendant actively concealed the true risks associated with the use of Elmiron, particularly as they related to the risk of serious vision-related injuries, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warning required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron.

131. Due to absence of any warnings by the Defendants as to the significant health and safety risks posed by Elmiron, Plaintiff was unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to her, her healthcare providers, or the general public.

132. Due to the absence of any instructions for how to identify and/or monitor Elmiron patients for potential vision-related complications, Plaintiff was unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to her, her healthcare providers, or the general public.

133. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, her healthcare providers, and the general public with respect to the safety and efficacy of Elmiron, Defendants are estopped from relying on any statute of limitations defenses.

MALPRACTICE AND OTHER CLAIMS AGAINST HEALTH CARE PROVIDERS

134. Plaintiff incorporates by reference all relevant paragraphs hereof as if fully set forth here and further alleges as follows:

135. During the time that Plaintiff was under the medical care and subject to treatment by Dr. Mohammad F. Ismail, A and B, defendants herein, did breach the applicable standard of care in his performance of his responsibilities in failing to exercise that level and standard of care expected from a normal and reasonable physician in like circumstances with regard to patient care, and other problems or failure and related issues, and in otherwise performing his duties and functions under the circumstances of his care and treatment of plaintiff.

136. While under the care of Dr. Mohammad F. Ismail, A and B, defendants herein, did commit acts of actionable negligence with regard to, and in his care and treatment of, plaintiff. Said defendant negligently failed to use reasonable care in selection of a proper medication for the treatment of her IC-related pain and her condition through a nursing staff or other personnel, or procedures or directives for examination, and other investigation of the suggested treatment for, and other matters relating to, the plaintiff, with regard to the treatment of her IC-related pain.

137. The conduct, acts, and omissions of Defendant, Dr. Mohammad F. Ismail, A and B, combined and concurred with acts of negligence, wantonness, breach of duty, and other tort and breach of contract by the other defendants herein, and of others, to proximately cause the pain and suffering experienced by plaintiff, her personal and vision-related injuries.

138. Defendants Dr. Mohammad F. Ismail and fictitious defendants had a duty to exercise reasonable care in the determination of the medical care Plaintiff should have received, including a duty to assure that the care she received did not cause plaintiff to suffer from unreasonable, dangerous side effects. Said Defendants failed to exercise ordinary care in the selection of medication for Plaintiff for treatment of her IC-related pain which created a high risk of unreasonable dangers and dangerous side effects, and in fact subjected her to personal injury, which constitute Defendants' negligence, wantonness, malpractice, assault, battery, breaches of contract and of warranty and conspiracy.

139. Said Defendants were negligent and wanton in the performing professional services for Plaintiff, in that they:

a. Failed to use due care, diligence and skill so as to avoid the unnecessary risk to Plaintiff;

b. Failed to warn Plaintiff of aforesaid side effects which can cause serious health risks;

c. Were otherwise careless or negligent.

140. As a consequence of Defendants' negligence, Plaintiff was diagnosed serious visual injuries, including, but not limited to, severe vision degradation, and loss of night vision. Accordingly, Defendants are jointly and severally liable to Plaintiff, for damages as allowed by law for the injury to her eyes, as provided by Alabama law.

141. Defendants' conduct rises to a level of conscious disregard for their duties and for the health, safety and well being of the Plaintiff. Defendants' conduct was negligent, reckless and wanton.

ADDITIONAL CAUSES OF ACTION

COUNT I

PRODUCTS LIABILITY UNDER AEMLD AND OTHER LAW

142. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

143. Defendants designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the Elmiron. All Defendants, who designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the said products into the stream of commerce each had an opportunity to inspect the products which were superior to the knowledge or opportunity of the consumer, Plaintiff herein.

144. The Elmiron sold and manufactured by the Defendants were defective and unreasonably dangerous in design, manufacture and/or fabrication in that, when they left the hands of the Defendants as manufacturers, sellers, designers, testers, marketers, distributors, promoters, and/or suppliers the foreseeable risks exceeded the benefits associated with the design or fabrication and they were unreasonably dangerous and defective. Plaintiff shows that she suffered injury or damages as a result of the sale by Defendants who sold the product in defective condition unreasonably dangerous to the ultimate consumer, and all the sellers were engaged in the business of selling such product and the product was expected to and did reach the user or consumer without substantial change in condition in which it was sold.

145. In addition or alternatively, Elmiron, manufactured and sold by Defendants, and fictitiously designated defendants and/or supplied by them was

defective in manufacture, design or formulation, in that, when it left the hands of the manufacturers, sellers, and/or suppliers, it was unreasonably dangerous, in that it did not meet the reasonable expectations of the ordinary consumer, and was more dangerous than an ordinary consumer would expect and more dangerous than other relevant devices. The plaintiff shows that the product was unreasonably dangerous and defective when it left the defendants' control, that it was substantially unaltered when the plaintiff used it, and that it proximately caused the plaintiff's injuries.

146. Elmiron manufactured and sold by Defendants was also defective due to inadequate warning or instruction because the manufacturers and suppliers knew or should have known that the products created a risk of harm to consumers and the Defendants failed to adequately warn of said risks.

147. Elmiron reached the consumer without substantial change in condition in which it was sold and used as intended by the defendants.

148. Elmiron is not fit for its intended purpose and does not meet reasonable expectations of the ordinary consumer.

149. Elmiron manufactured and sold by Defendants was defective due to inadequate warning and/or inadequate testing.

150. Elmiron manufactured and sold by Defendants was also defective due to inadequate marketing and post-marketing warnings or instruction because, after the Defendants knew or should have known of the risk of injury from Elmiron from use, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

151. As a consequence of the above-described producing cause and as a legal

result of the dangerous and defective condition of the Elmiron which was designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants, and as a direct and legal result of the tort, AEMLD violation, negligence, carelessness, other wrongdoing and actions of Defendants described herein:

a. Plaintiff has been injured in health, strength and activity and suffered injuries to body and mind, the full nature and extent of which are not known at this time;

b. Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

SURGICAL MESH

152. Defendants designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the surgical mesh. All Defendants, who designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the said products into the stream of commerce each had an opportunity to inspect the products which were superior to the knowledge or opportunity of the consumer, Plaintiff herein.

153. The surgical mesh sold and manufactured by the Defendants were defective and unreasonably dangerous in design, manufacture and/or fabrication in that, when they left the hands of the Defendants as manufacturers, sellers, designers, testers, marketers, distributors, promoters, and/or suppliers the foreseeable risks

exceeded the benefits associated with the design or fabrication and they were unreasonably dangerous and defective. Plaintiff shows that she suffered injury or damages as a result of the sale by Defendants who sold the product in defective condition unreasonably dangerous to the ultimate consumer, and all the sellers were engaged in the business of selling such product and the product was expected to and did reach the user or consumer without substantial change in condition in which it was sold.

154. In addition or alternatively, the Defendants' surgical mesh, manufactured and sold by RMC, and fictitiously designated defendants and/or supplied by them was defective in manufacture, design or formulation, in that, when it left the hands of the manufacturers, sellers, and/or suppliers, it was unreasonably dangerous, in that it did not meet the reasonable expectations of the ordinary consumer, and was more dangerous than an ordinary consumer would expect and more dangerous than other relevant devices. The plaintiff shows that the product was unreasonably dangerous and defective when it left the defendants' control, that it was substantially unaltered when the plaintiff used it, and that it proximately caused the plaintiff's injuries.

155. The surgical mesh manufactured and sold by Defendants was also defective due to inadequate warning or instruction because the manufacturers and suppliers knew or should have known that the products created a risk of harm to consumers and the Defendants failed to adequately warn of said risks.

156. The surgical mesh reached the consumer without substantial change in condition in which it was sold and used as intended by the defendants.

157. Defendant's surgical mesh is not fit for its intended purpose and does not meet reasonable expectations of the ordinary consumer.

158. The surgical mesh manufactured and sold by Defendants was defective due to inadequate warning and/or inadequate testing.

159. The surgical mesh manufactured and sold by Defendants was also defective due to inadequate marketing and post-marketing warnings or instruction because, after the Defendants knew or should have known of the risk of injury from surgical mesh from use of these devices, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

160. As a consequence of the above-described producing cause and as a legal result of the dangerous and defective condition of the surgical mesh which designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants, and as a direct and legal result of the tort, AEMLD violation, negligence, carelessness, other wrongdoing and actions of Defendants described herein:

a. Plaintiff has been required to undergo further surgery and has been injured in health, strength and activity and suffered injuries to body and mind, the full nature and extent of which are not known at this time;

b. Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

COUNT II

NEGLIGENCE

161. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

162. Defendants, directly or indirectly, caused Elmiron to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Elmiron within this judicial district and aimed at a consumer market within this district.

163. At all relevant times, Defendants owed a duty to the general public, and specifically to the Plaintiff and her healthcare providers, to exercise reasonable care in the design, research, study, testing, development, manufacture, labeling, promotion, sale, marketing, and distribution of their prescription medications, including Elmiron, at issue in this lawsuit.

164. Defendants failed to exercise reasonable care in the design of Elmiron, because as designed, it was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

165. Defendants failed to exercise reasonable care in the marketing of Elmiron because they failed to warn that, as designed, Elmiron was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

166. Defendants knew or, in the exercise of reasonable care, should have known that use of Elmiron could cause or be associated with Plaintiff's injuries, and thus, create

a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

167. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Elmiron were unaware of the risks and the magnitude of the risks associated with use of Elmiron.

168. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

a. By failing to use due care in developing, testing, designing and manufacturing Elmiron so as to avoid the aforementioned risks to individuals when Elmiron was being used for treatment;

b. By failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Elmiron and the comparative severity and duration of such adverse effects;

c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

d. By failing to accompany their products with proper or adequate rate of incidence or prevalence of eye damage;

e. By failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

f. By failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Elmiron;

g. By failing to warn Plaintiff, the medical and healthcare community,

and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

h. By failing to provide adequate training or information to medical care providers for appropriate use and handling of Elmiron, and patients taking Elmiron;

i. By failing to adequately test and/or warn about the use of Elmiron, including, without limitations, the possible adverse side effects and health risks caused by the use of Elmiron;

j. By failing to design and/or manufacture a product that could be used safely;

k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;

l. By failing to remove Elmiron, from the market when Defendants' knew or should have known of the likelihood of serious and permanent side effects and injury to its users;

m. By failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of pigmentary maculopathy, permanent eye damage, and related conditions to individuals taking Elmiron; and

n. In representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

169. The Elmiron that injured Plaintiff was in substantially the same condition when Plaintiff used Elmiron as it was in when it left the control of Defendants. Elmiron's

ability to cause serious and permanent personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff used Elmiron as directed and without change in its form or substance.

170. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Elmiron was a proximate cause of Plaintiff's injuries and damages.

171. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

SURGICAL MESH

172. Defendants and fictitious defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of surgical mesh into the stream of commerce, including a duty to assure that the products did not cause users to suffer from injuries unreasonable, dangerous side effects. Said Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of surgical mesh into interstate commerce in that said Defendants knew or should have known that the products, the surgical mesh created a high risk of unreasonable dangers and dangerous side effects, some of which can be fatal or crippling.

173. Said Defendants were negligent in the design, development, manufacturing, testing, marketing, distributing, implanting, promoting, and sale of surgical mesh in that they:

a. Failed to use due care in designing and manufacturing surgical mesh so as to avoid the aforementioned risks to individuals when surgical mesh were being used for implantation;

b. Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of surgical mesh and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

c. Failed to conduct adequate pre-clinical and clinical testing and post-marking surveillance to determine the safety of the surgical mesh;

d. Failed to provide adequate training to medical care providers for appropriate use of surgical mesh ;

e. Failed to warn physicians or Plaintiff, prior to actively encouraging the sale of surgical mesh either directly or indirectly, orally or in writing, about the following: (1) about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal complications; (2) the danger of complications; (3) the dangers of the consequences of complications; (4) proper installation of the surgical mesh;

f. Failed to warn Plaintiff, physicians and general public of aforesaid side effects and complications, which can cause serious health risks;

g. Failed to warn that the costs associated with surgical mesh could exceed other comparable forms of implantation, particularly for those who were like plaintiff; and

h. Were otherwise careless or negligent.

174. Despite the fact that said Defendants knew or should have known that surgical mesh caused unreasonable, dangerous complications which many users would be impotent to remedy by any means, said Defendants continued to market surgical mesh including to Plaintiff's health care providers, when there were safer alternative

methods of treatment available.

175. Said Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of said Defendants' failure to exercise ordinary care as described above.

176. Said Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which she suffered and will continue to suffer as previously described. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

COUNT III

PRODUCT LIABILITY (FAILURE TO WARN)

177. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

178. At all relevant times, Defendants advertised and promoted the use of Elmiron as a safe method of treatment for IC despite the lack of adequate testing for either safety or efficacy and after it knew or reasonably should have known that Elmiron suffered from design and/or manufacturing defects.

179. Despite the fact that evidence existed that the use of Elmiron was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Elmiron and in fact, acted to deceive the medical community and public at large, including all potential users

of Elmiron by promoting it as a safe and effective method of treatment for IC, when, in fact, it was unsafe and alternative and safer methods for pharmacological treatment existed.

180. Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that Elmiron created, among other things, a significantly increased risk of permanent and disfiguring eye damage by consumers and Defendants failed to adequately warn of said risks and the severity of such adverse effects, resulting in harm to Plaintiff, as set forth, herein.

181. Defendants failed to warn physicians and users of Elmiron of the aforementioned dangers and adverse side effects.

182. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

183 Defendants are designers, developers, manufacturers, testers, marketers, distributors, implantors, promoters, and sellers of the following: surgical mesh.

184. The surgical mesh designed, developed, manufactured, tested, marketed,

distributed, implanted, promoted, and sold by Defendants were and are unaccompanied by proper warnings regarding all possible adverse side effects associated with the use of surgical mesh and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

185. Defendants failed to perform adequate testing in that adequate testing would have shown that surgical mesh used individually and/or in any combination thereof, possessed serious potential hazards with respect to which full and proper warnings accurately and fully reflecting hazards, symptoms, scope and severity should have been made, both with respect to the use of any of the surgical products.

186. Defendants also failed to effectively warn users and physicians that numerous other devices made by other manufactures did not cause complications such as mesh erosion, pain, infection, bleeding, pain during sex, organ perforation and urinary problems, many of which require additional treatment, including surgery, as did the subject surgical mesh.

187. The surgical mesh designed, developed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants was defective due to inadequate post-marketing warning or instruction because, after the manufacturer, developer, designer, and marketer knew or should have known of the risk of injury from the surgical mesh it and they failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote the product, and no accurate or appropriate warning was given to Plaintiff or her physicians by Defendants RMC or the other defendants at the point and time of sale or implantation or by anyone else.

188. The producing cause and legal result of the dangerous and defective condition of the surgical mesh as designed, developed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:

a. Plaintiff has been injured in health, strength and activity and suffered injuries to body and mind, the exact nature and extent of which are not known at this time;

b. Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff required reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

COUNT IV

DEFECTIVE DESIGN

189. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

190. At all times relevant herein, Defendants placed Elmiron into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for the intended purpose. Insofar as Elmiron could not be used safely without the unreasonable

risk of harm, it was ineffective for the purpose for its intended use, i.e., the treatment of IC-related pain.

191. At all times relevant herein, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron.

192. Elmiron is defective in its design or formulation in that it is not reasonable fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

193. At all times relevant herein, Elmiron was expected to reach, and in fact did reach, consumers in the Calhoun County in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

194. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the control of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

195. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate pre-market and post-market testing.

196. At all times relevant herein, Defendants intended for its Elmiron to be used as a superior form of treatment for IC, despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendants' widespread promotional activity, physicians began commonly prescribing Elmiron as a safe and effective treatment for IC-related pain.

197. As a direct and proximate result of one or more of these wrongful acts or

omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

198. Alternatively, the Elmiron designed, marketed, manufactured and/or supplied by Defendants were defective in design, for the intended patient population, due to the low bioavailability of the drug.

199. Alternatively, Elmiron that was manufactured, marketed, supplied and/or sold by Defendants and prescribed to and used by Plaintiff was defective in design, manufacture or formulation in that when it left the hands of the manufacturer and/or supplier/seller, it was unreasonably dangerous, and was more dangerous than an ordinary consumer would expect and more dangerous than other methods of treatment for IC-related pain.

200. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns, including adverse event reports—both in the United States and around the world, where Elmiron was sold—and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

201. Defendants improperly, negligently, falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Elmiron to and/or from FDA, that had FDA known of such facts, Elmiron would have never been approved and no physician would have

been able to prescribe Elmiron to Plaintiff.

202. Defendant improperly, negligently, falsely, and deceptively misrepresented and/or knowingly omitted, suppressed, and/or concealed facts of such materiality regarding the safety and efficacy of Elmiron to and/or from FDA, that had FDA known of such facts, Elmiron would have never been approved with the warnings and instructions for use that accompanied Elmiron and/or were provided to prescribing physicians and the public, so that Elmiron would not have been prescribed to nor used by Plaintiff.

203. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, no statutory presumptions in favor of Defendants are warranted.

204. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

205. At all times relevant herein, Defendants placed surgical mesh

into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for the intended purpose. Insofar as surgical mesh could not be used safely without the unreasonable risk of harm, it was ineffective for the purpose for its intended use.

206. At all times relevant herein, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling surgical mesh.

207. Surgical mesh is defective in its design or formulation in that it is not reasonable fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

208. At all times relevant herein, surgical mesh was expected to reach, and in fact did reach, consumers in the Calhoun County in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

209. The surgical mesh designed, marketed, manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the control of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

210. The surgical mesh designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate pre-market and post-market testing.

211. At all times relevant herein, Defendants intended for its surgical mesh to be used as a superior form of treatment, despite their failure to test or otherwise

determine the safety and efficacy of such use. As a direct and proximate result of Defendants' widespread promotional activity, physicians began commonly using surgical mesh as a safe and effective treatment.

212. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

213. Alternatively, the surgical mesh designed, marketed, manufactured and/or supplied by Defendants was defective in design.

214. Alternatively, surgical mesh that was manufactured, marketed, supplied and/or sold by Defendants and prescribed to and used by Plaintiff was defective in design, manufacture or formulation in that when it left the hands of the manufacturer and/or supplier/seller, it was unreasonably dangerous, and was more dangerous than an ordinary consumer would expect and more dangerous than other methods of treatment.

215. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns, including adverse event reports—both in the United States and around the world, where surgical mesh was sold—and to deliberately not study the long-term safety and efficacy of surgical mesh.

216. Defendants improperly, negligently, falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of surgical mesh to and/or from FDA, that had FDA

known of such facts, surgical mesh would have never been approved and no physician would have been able to prescribe surgical mesh to Plaintiff.

217. Defendant improperly, negligently, falsely, and deceptively misrepresented and/or knowingly omitted, suppressed, and/or concealed facts of such materiality regarding the safety and efficacy of surgical mesh to and/or from FDA, that had FDA known of such facts, surgical mesh would have never been approved with the warnings and instructions for use that accompanied surgical mesh and/or were provided to prescribing physicians and the public, so that surgical mesh would not have been used by Plaintiff.

218. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, no statutory presumptions in favor of Defendants are warranted.

219. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

COUNT V

MANUFACTURING DEFECT

220. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

221. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron.

222. At all times relevant herein, Elmiron was expected to reach, and did reach, consumers in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

223. Elmiron use by Plaintiff for IC was reasonably foreseeable and was used in the manner for which it was intended by the Defendants.

224. At all times relevant herein, Elmiron was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, Elmiron contained manufacturing defects which rendered the product unreasonably dangerous and subjected Plaintiff to risks that exceed the benefits of Elmiron, including but not limited to the risks of developing serious and dangerous side effects, and other severe and permanent health consequences;

b. Elmiron manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Elmiron was not made in accordance with Defendants' specifications or performance standards; and

d. Elmiron manufacturing defects existed before it left the control of Defendants.

225. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured and will continue to endure substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

226. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling surgical mesh.

227. At all times relevant herein, surgical mesh was expected to reach, and did reach, consumers in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

228. Surgical mesh use by Plaintiff was reasonably foreseeable and was used in

the manner for which it was intended by the Defendants.

229. At all times relevant herein, surgical mesh was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, surgical mesh contained manufacturing defects which rendered the product unreasonably dangerous and subjected Plaintiff to risks that exceed the benefits of surgical mesh, including but not limited to the risks of developing serious and dangerous side effects, and other severe and permanent health consequences;

b. surgical mesh manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. surgical mesh was not made in accordance with Defendants' specifications or performance standards; and

d. surgical mesh manufacturing defects existed before it left the control of Defendants.

230. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured and will continue to endure substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically,

emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

COUNT VI

BREACH OF IMPLIED WARRANTIES

231. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

232. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Elmiron in the course of same, directly advertised or marketed the product to FDA, health care professionals and consumers, including Plaintiff, or person responsible for consumer.

233. Defendants are merchants with respect to consumer medication like Elmiron and impliedly warranted their Elmiron which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

234. Defendants failed to disclose that Elmiron has dangerous propensities when used as intended and that use of Elmiron carries an increased risk of developing severe injuries, including Plaintiff's injuries.

235. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers of Elmiron.

236. Elmiron was expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendants.

237. Defendants intended that Elmiron be used in the manner in which Plaintiff, in fact, used it and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Elmiron was not adequately tested or researched.

238. In reliance upon Defendants' implied warranty, Plaintiff used Elmiron as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

239. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Elmiron.

240. Defendants breached their implied warranty to Plaintiff in that Elmiron was not of merchantable quality, safe, or fit for their intended use, or adequately tested. Elmiron has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein

241. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

242. At the time Defendants marketed, sold, and distributed the surgical mesh for use by Plaintiff, Defendants knew of the use for which the surgical mesh were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

243. Plaintiff received the implied warranty from Defendants and Plaintiff had no skill and no basis on which to form an independent judgment as to the product of Defendants as to whether the surgical mesh was of merchantable quality, safe and fit for its intended use.

244. Contrary to such implied warranty the surgical mesh was not of merchantable quality, safe or fit for its intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purpose for which they were used as described above. Defendants otherwise breached the implied warranty.

245. As a direct and proximate result of the breach of implied warranty, Plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

COUNT VII

BREACH OF EXPRESS WARRANTIES

246. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

247. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Elmiron in the course of same, directly advertised or marketed the product to FDA, health care professionals and consumers, including Plaintiff, or person responsible for consumer.

248. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Elmiron, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Elmiron, when making representations to consumers and the general public, including Plaintiff.

249. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Elmiron was safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted Elmiron, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Elmiron would conform to the representations.

250. The representations about Elmiron, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

251. Elmiron, materially failed to conform to those representations made by Defendants in Package Inserts, and otherwise, concerning the properties and effects of Elmiron respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and used with in direct or indirect reliance upon these express warranties made, directly or indirectly, to Plaintiff concerning Elmiron sold to Plaintiff.

252. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

253. Defendants expressly warranted that surgical mesh was safe and well accepted by patients studied, and free from a danger of complications.

254. The subject surgical mesh does not conform to these express representations because it is not safe and has high levels of serious dangers, including life threatening side effects of complications, and did in fact cause severe complications

including surgery for removal of the surgical mesh.

255. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

COUNT VIII

FRAUDULENT CONCEALMENT

256. Plaintiff incorporates by reference all other relevant paragraphs into this Count as if fully set forth herein and further alleges as follows:

ELMIRON

257. At all times, during the course of, dealing between Defendants, Plaintiff, and Plaintiff's healthcare providers, Defendants misrepresented the safety of Elmiron.

258. At all times, during the course of, dealing between Defendants, Plaintiff, and Plaintiff's healthcare providers, Defendants misrepresented the safety of Ethicon.

259. Defendants knew or was reckless in not knowing that its representations were, in fact, false.

260. In representations to Plaintiff and Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. Elmiron was not as safe as other similar drugs and medications indicated for the treatment of IC;

b. Elmiron was defective, and it caused dangerous side effects;

c. Elmiron was manufactured negligently;

d. Elmiron was manufactured defectively;

e. Elmiron was manufactured improperly;

f. Elmiron was designed negligently;

g. Elmiron was designed defectively;

h. Elmiron was designed improperly.

261. Defendants were under a duty to disclose to Plaintiff and Plaintiff's healthcare providers the defective nature of Elmiron including but not limited to the risk of developing vision loss.

262. Defendants had sole access to material facts concerning the defective nature of Elmiron and its propensity to cause vison damage and/or loss.

263. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Elmiron was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the Elmiron, and to cause them to purchase, prescribe, dispense and/or use the product.

264. Defendants knew that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendants; concealment and omissions, as set forth herein.

265. Plaintiff, as well as Plaintiff's physicians, hospital and healthcare providers, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

266. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

SURGICAL MESH

267. At all times, during the course of, dealing between Defendants, Plaintiff, and Plaintiff's healthcare providers, Defendants misrepresented the safety of surgical mesh.

268. At all times, during the course of, dealing between Defendants, Plaintiff, and Plaintiff's healthcare providers, Defendants misrepresented the safety of their surgical mesh.

269. Defendants knew or was reckless in not knowing that its representations were, in fact, false.

270. In representations to Plaintiff and Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. Surgical mesh was not as safe as other similar devices indicated for treatment;

b. Surgical mesh was defective, and it caused dangerous side effects;

c. Surgical mesh was manufactured negligently;

d. Surgical mesh was manufactured defectively;

e. Surgical mesh was manufactured improperly;

f. Surgical mesh was designed negligently;

g. Surgical mesh was designed defectively;

h. Surgical mesh was designed improperly.

271. Defendants were under a duty to disclose to Plaintiff and Plaintiff's healthcare providers the defective nature of surgical mesh including but not limited to the risk of developing serious complications.

272. Defendants had sole access to material facts concerning the defective nature of surgical mesh and its propensity to cause serious complications, damage and/or loss.

273. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of surgical mesh was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the surgical mesh, and to cause them to purchase, prescribe, dispense and/or use the product.

274. Defendants knew that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendants; concealment and omissions, as set forth herein.

275. Plaintiff, as well as Plaintiff's physicians, hospital and healthcare providers, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

276. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

COUNT IX

MISREPRESENTATION, FRAUD, SUPPRESSION AND DECEIT

277. Plaintiff incorporates by reference all other paragraphs as if fully set forth here and further alleges as follows:

278. Plaintiff alleges on information and belief that even if misrepresentations made by Defendants were innocent misrepresentations, they are nonetheless actionable under Alabama and other law. Defendants have made and some of them continue to make false and fraudulent misrepresentations to Plaintiff, physicians and general public including, but not limited to, that the products were safe, fit and effective for use and its components were not hazardous to the health of users.

279. At all pertinent times, Defendants conducted, and/or conspired jointly to conduct, a sales and marketing campaign to promote the sale of their products through advertisements and other promotional literature and fraudulently deceived the Plaintiff, physicians and the general public as to the health risks and consequences of their products. Defendants also failed to disclose other effective methods for treatment.

Defendants suppressed material facts that, if disclosed to Plaintiff would have resulted in Plaintiff's refusal to use the products.

280. Defendants misrepresentation and suppressions of material facts were done intentionally, willfully and/or negligently. Plaintiff and her physician reasonably relied upon the skill and judgment of said Defendants as to whether the products were of merchantable quality, safe and fit for their intended uses.

281. In reliance of the foregoing misrepresentation whether innocent, negligent or not by Defendants, Plaintiff was induced to and did subject herself to the use of the products. If the Plaintiff had known the true facts, she would not have taken such action and subjected herself to the aforesaid risks.

282. As a result of Defendants' negligence, false and fraudulent misrepresentation, fraudulent suppression and concealment, and conspiracy, Plaintiff has suffered harm, injuries and damages as described above. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

DAMAGES

283. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that fairly and reasonably compensates Plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort of Plaintiff;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and Post Judgment Interest;

g. Exemplary and Punitive Damages; and

h. Such other damages and relief to which Plaintiff may be justly entitled.

WHEREFORE, the Plaintiff demands judgment against each Defendant, named and fictitious, jointly and severally, in such sums of compensatory and punitive damages as are determined to be fair, just, and lawful, plus costs of this civil action.

/s/ Steve R. Morris
Steve R. Morris
Attorney for Plaintiffs
Steve R. Morris Law
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/s/ Victoria Wilson
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Anniston, AL 36201
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Defendants may be served at the following address:

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C T Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

Dr. Mohammad F. Ismail
1011 Leighton Avenue
Anniston, AL 36207

Teva Branded Pharmaceutical Products R&D, Inc.
41 Moores Rd.
Frazer, PA 19355

Teva Pharmaceuticals USA, Inc.
1090 Horsham Road,
North Wales, Pennsylvania, 19454.

Defendant Teva Pharmaceutical Industries Ltd.
U.S. Headquarters
400 Interpace Parkway, #3
Parsippany, New Jersey 07054

Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road
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Ortho-McNeil Pharmaceuticals, Inc.
1000 US Highway 202
Raritan, New Jersey 08869

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